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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/203,548	12/01/98	GOLI S	PF-0233-1-DI

EXAMINER

HM22/0802

LUCY J BILLINGS
INCYTE PHARMACEUTICALS
3174 PORTER DRIVE
LEGAL DEPARTMENT
PALO ALTO CA 94304

PAK, M

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 08/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/203,548	Goli et al.
Examiner	**Group Art Unit**
Michael Pak	1646

☒ Responsive to communication(s) filed on *Apr 21, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *18-42* is/are pending in the application.

Of the above, claim(s) *20-32 and 35-42* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *18, 19, 33, and 34* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Preliminary amendments filed 1 December 1998(Paper No. 2 and 3) and filed 21 April 2000 (paper No. 8) have been entered.

Election/Restriction

2. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that all the groups can be examined without undue burden on the Examiner. This is not found persuasive because as discussed in the previous office action the groups are classified separately. Furthermore, groups III and V classification could not be determined which is clearly a burden on the examiner to search and examine. Applicants further argue that groups IV and V should be rejoined and examined with the claims of groups I and III. Since group III will not be rejoined for the reasons set forth above the method of group V which uses the product of Group III cannot be rejoined with group I. The rejoinder of the process group III will be considered when claims of Group I are allowed and the procedures set forth in MPEP 821.04 will be followed.

The requirement is still deemed proper and is therefore made FINAL.

3. Newly submitted claims 20-32 and 35-42 are directed to an

invention that is independent or distinct from the invention originally claimed for the following reasons:

II. Claim 32, drawn to a purified antibody, classified in Class 530, subclass 387.1.

III. Claims 37-38, drawn to a purified antagonist, classification could not be determined because no structure is provided.

IV. Claim 35, drawn to a method for treating a developmental disorder by administering a pharmaceutical composition comprising cytokine/steroid receptor, classified in Class 514, subclass 2.

V. Claim 39, drawn to a method for treating a disorder by administering an antagonist, classification could not be determined because no structure is provided.

VI. Claims 20-28, drawn to an isolated polynucleotide, expression vector, host cell, and method of producing the polypeptide, classified in Class 536, subclass 23.5.

VII. Claims 29-30, drawn to a method for detecting a target polynucleotide by hybridization, classified in Class 435, subclass 6.

VIII. Claim 31, drawn to a method for detecting a target polynucleotide by PCR, classified in Class 435, subclass 6.

IX. Claim 36, drawn to a purified agonist, classification could not be determined because no structure is provided.

X. Claim 40, drawn to a method for screening a compound as an agonist, classified in Class 435, subclass 7.2.

XI. Claim 41, drawn to a method for screening a compound as an antagonist, classified in Class 435, subclass 7.2.

XII. Claim 20, drawn to a method for screening a compound in altering expression, classified in Class 435, subclass 6.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-32 and 35-42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

4. The information disclosure statement filed 1 December 1998 (Paper No.2) fails to comply in part with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because references 14 and 20 did not cite the date of the reference. The examiner entered the date for the applicant in the form 1449.

5. The information disclosure statement filed 1 December 1998 (Paper No.2) fails to comply in part with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed;

and all other information or that portion which caused it to be listed. References 1-2 and 15-18 were not provided and has not been cited in 08/822,264. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 18-19 and 33-34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a polypeptide comprising SEQ ID NO:1 and its variants in claim 18 limitations where the polypeptide is a receptor for which the function is not known. Although the closest prior art (Falkenstein et al.(10)) teach that the protein binds progesterone, the protein is not the

traditional progesterone steroid receptor which translocates to the nucleus which is well known. Rather the protein is only identified by binding characteristic which does not reveal its function. The specification as filed does not disclose or provide evidence that points to a property of the claimed receptor such that another non-asserted utility would be well established. Since the function of the protein is not known, the protein lacks well established utility. The specification on page 3 disclose the asserted utility of using the polypeptide in treating disorders associated with aberrant cellular development and differentiation and inflammation. However, there is no nexus between the unknown properties of the polypeptide and the treatment of the disease. Thus, the treatment of the disease lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed method using the polypeptide does not have well established utility because different polypeptide would have different functions and the skilled artisan would have to determine the function of the polypeptide. The claimed polypeptides do not substantial utility because the

skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the polypeptide of the claimed invention is generally applicable to any polypeptide and therefore is not particular to the polypeptide claimed.

Claims 18-19 and 33-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention.

Claim 18 limitation (b) encompass a protein encoded by an allelic variant because of the recitation of a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1. Thus, claims encompass a subgenus of "naturally occurring allelic variants" which is not disclosed in the specification. The ordinary meaning of the term allele is one of two or more alternate forms of a gene occupying the same locus in a particular chromosome or linkage structure and differing from other alleles of the locus at one or more mutation sites (see Rieger et al., *Glossary of Genetics* (1991), pages 16-17). However, the specification only discloses one subgenus of the human polypeptide. Furthermore, the species for the human is not known because some of the amino acids are represented by Xaa for any amino acids or unknown amino acids. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is they are variant structures and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the

genus and is insufficient to support the claim.

Claim 18 limitation (b) recitation of a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 is new matter because the subgeneric invention is not disclosed in the specification. The specification disclose the genus of a polypeptide which has 90% sequence identity and the species of SEQ ID NO:1 but does not disclose the subgeneric invention of claim 18 limitation (b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 18 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedberg et al.(19).

Friedberg et al. disclose a CYP2B12 (pages 778-779, figures

3 and 6).

Claims 18 and 33 encompass a "biologically active fragment" and an "immunogenic fragment". Friedberg et al. disclose a CYP2B12 which has 4 amino acid sequence identical to SEQ ID NO:1. The buffers are pharmaceutically acceptable excipient.

10. Claims 18 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Meyer et al.(11) as evidenced by Falkenstein et al.(10).

Meyer et al. disclose the progesterone binding protein (Figures 1-4).

Falkenstein et al. disclose a porcine progesterone membrane binding protein (pages 86-89).

Claims 18 and 33 encompass a "biologically active fragment" and an immunogenic fragment. Meyer et al. Pprotein inherently has the amino acid sequence taught by Falkenstein et al. Falkenstein et al. teach that the protein which has 93% amino acid sequence identical to SEQ ID NO:1. The buffers are pharmaceutically acceptable excipient.

11. Claims 18 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al.((A); US 5,976,837).

Jacobs et al. disclose a porcine progesterone membrane binding protein and pharmaceutically acceptable excipient

(columns 3-4, 14-15, 20-21, 23-24, and 39-40).

Claims 18 and 33 encompass a "biologically active fragment" and an immunogenic fragment. Jacobs et al. disclose a protein which has 93% amino acid sequence identical to SEQ ID NO:1.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Selmin et al.(9) is cited as cumulative references with Falkenstein et al.(10).

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
12 July 2000